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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,248	01/25/2005	Yasuo Hino	4578-0113PUS1	8811
2292	7590	03/01/2006	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			ROBERTS, LEZAH	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 03/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/522,248	<b>Applicant(s)</b> HINO ET AL.	
	<b>Examiner</b> Lezah W. Roberts	<b>Art Unit</b> 1614	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>25 Jan 2005</u> . | 6) <input type="checkbox"/> Other: ____.  |

## DETAILED ACTION

### *Claims*

#### **Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1) Claims 5, 10-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims are indefinite insofar as the basis for the percent calculation is not set forth, e.g., percent by weight based on the total weight of the composition, percent by volume based on the volume of the carrier, etc. See Honeywell Intl. v. Intl. Trade Commn., 341 F.3d 1332, 1340 (Fed. Cir. 2003). (Holding that where a claimed value varies with its method of measurement and several alternative methods of measurement are available, the claimed value is indefinite unless the particular method of measurement is recited.) The percent calculation must either be clearly defined within the specification or set forth within the claim.

2) Claims 5 and 10-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 5 and 11-16 recites the limitation

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"compounding ratio" in the second and third lines of the claims. There is insufficient antecedent basis for this limitation in the claim.

### **Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1) Claims 1-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Heyd et al. (US 4,315,779).

Heyd et al. discloses non-adhesive gel compositions for stabilizing dentures. The compositions contain a hydrophilic cellulose polymer, a demulcent and water, as recited in claims 1 and 6. The hydrophilic cellulose polymer may be selected from a group containing hydrophilic cellulose polymers or alginates. These groups include methylcellulose, ethylcellulose, methylethylcellulose, carboxymethylcellulose, hydroxyethylcellulose, hydroxypropylcellulose and the like as well as the water-soluble salts of the cellulose polymers, such as for example, sodium carboxymethylcellulose, sodium carboxyethylcellulose and sodium carboxymethylhydroxyethylcellulose, as recited in claims 2, 4, 7 and 9. The polymer may be incorporated into the compositions in an amount ranging from 1% to 10% by weight (col. 2, lines 22-68). The demulcents,

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or polyvalent alcohols as it is referred to in the instant claims, may be selected from a group containing glycerine, sorbitol and propylene glycol, which encompasses claims 3, 4, 8 and 9. They are included in the composition in a concentration ranging from 5% to 40% by weight. The preferred demulcent is glycerine (col. 3, lines 22-27). The water comprises 50% to 95% by weight of the composition (col. 2, lines 7-8). Other components may be added to the compositions such as sodium chloride. Sodium chloride can be added to the compositions to adjust the tonicity of the composition (col. 28-31). The table in column 4 encompasses claims 5 and 10-16. The reference anticipates the instant claims insofar as it discloses a composition containing a water-soluble polymer, a pharmaceutically acceptable polyvalent alcohol and water and/or artificial saliva.

2) Claims 1-3, 5-8, 10-12 and 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Cornell (US 4,233,288).

Cornell teaches chewing gum compositions to treat patients with xerostoma. The compositions comprise a liquid portion comprising water wherein inorganic mineral salts in a total concentration of about 1% to 3% are dissolved. The salts include sodium, potassium, magnesium and calcium chlorides and potassium phosphates. Also included are fluoride ions as NaF ranging from 2 to 20 parts per million, which serves to prevent the demineralization of teeth. The mineral salt content or concentration may be adjusted to be isotonic, as is physiological salt solutions, may be hypotonic, e.g., less than physiological salt concentration or only slightly higher. Where saliva is lacking, as,

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for example, in xerostoma, the liquid emulsified gum composition is especially useful because the mineral salt solution in diluted form is released slowly by chewing (col. 2, lines 4-19). The gum also comprises glycerine ranging from 1% to 3% (col. 4, first table) and hydrophilic polymers such as carboxymethyl cellulose (CMC) and fibrous cellulose to adjust the rate of dispersion. The polymers comprise 3% to 5% of the composition (col. 4, first table). Sweeteners and flavors such as xylitol, sorbitol, maltitol or sweetener substitutes such as saccharine or aspartame are added to the compositions in amounts as little as 4% (col. 3, lines 7-14). Glycerine and carboxymethyl cellulose may be added to the liquid phase to increase viscosity, glycerine in amounts of from 0.25% to 2.5% and CMC in amounts of 0.2% to 2% (col. 3, 29-33). The gum is mixed by first mixing the liquid portion of the gum with the components stated above. Cellulose fibers and the inorganic fillers are added to the liquid solution. The liquid solution is then added to the gum base. The reference anticipates the instant claims insofar as it discloses a composition for wetting the mouth comprising a polyvalent alcohol, carboxymethyl cellulose, and water and/or artificial saliva. In regards to the composition of the prior art being able to act as a mouth wetting agent for false teeth, since the compositions of the reference are substantially the same, i.e., they include a polyvalent alcohol, a water-soluble polymer, and water and/or saliva substitute, as the wetting agent of the instant claims, accordingly the compositions of the reference should be able to act as a mouth wetting agent for false teeth.

3) Claims 1-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Morrow et al. (US 4,537,689).

Morrow et al. teaches oral lubricant compositions for athletic mouth protectors. The taught invention relates to reducing the discomfort of wearing mouth protectors through the use of lubricating compositions. By applying the lubricating composition to the mouth protector prior to insertion of the mouth protector into the oral cavity, the user will help prevent the drying of the oral cavity. The composition comprises a lubricating agent such as glycerin. The preferred lubricant is glycerin, however, it is expected that high molecular weight compositions such as propylene glycol or polyethylene glycol could be used in place of or in conjunction with glycerin (col. 2, lines 51-55), as recited in claims 1, 3-4, 6 and 8-9. The glycerin concentration ranges from 1% to 20%, calculated by the volumes used in the examples and volumes recited in the referenced claims. The composition also contains (1) a thickening agent, (2) a preservative, (3) a flavoring agent, (4) a sweetener, (5) an emulsifier, if needed, and (6) a diluent. Thickening agents are utilized to increase the viscosity of the composition. Depending upon the particular thickening agent utilized, the thickening agent can also help to maintain the stability of the composition and to enhance its emulsifying qualities. The preferred thickening agent used in the taught compositions is methylcellulose; particularly sodium carboxymethyl cellulose may be utilized because of its ability to solubilize readily (col. 2, lines 36-68), as recited in claims 1-2, 4, 6-7 and 9. Other hydrophilic polymers that may be used in the compositions include any hydrophilic polymer that has a viscosity higher than that of water and also has some lubricating

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properties. Hydrophilic polymers such as ethyl cellulose and other alkyl derivatives of these cellulose may also be used, as well as naturally occurring gums (acacia, any one of the alginates, tragacanth, agar, or guar gum), or a synthetic hydrophilic polymer, such as polyvinylpyrrolidone or one of the vinyl polymers (col. 3, lines 1-9). The concentration of the thickeners in the compositions ranged from about 0.45% to about 2.4% by weight (see claim 3 of the reference). The referenced claim uses the term about 2.4% therefore this range encompasses 3% as recited in the instant claims. The term "about" permits some tolerance. See, for example, In re Ayers, 69 USPQ 109 (CCPA 1946). The diluent reduces the concentrations of the active components to an effective level. Water has found to be particularly effective as a diluent (col. 3, lines 41-43). Disclosed compositions comprise glycerin, sodium carboxymethylcellulose or Veegum and water (example 1 and 2). The reference anticipates the instant claims insofar as disclosing a lubricating composition comprising a polyvalent alcohol, carboxymethyl cellulose, and water. In regards for the mouth wetting agent for false teeth, since the compositions of the reference are substantially the same, i.e., they include a polyvalent alcohol, a water-soluble polymer, and water and are used for wetting a mouth protector, as the wetting agent of the instant claims, which is also a wetting agent for false teeth which are placed in the mouth similarly to a mouth protector, accordingly the compositions of the reference should be able to act as a mouth wetting agent for false teeth.

4) Claims 1-5 and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Smitherman (US 5,015,467).



Smitherman teaches oral anti-calculus and anti-plaque compositions. These compositions include toothpastes. The compositions comprise a carboxy starch polymer incorporated at a concentration ranging from 0.1% to 5% by weight. Higher concentrations, e.g., 15% may be used if desired (col. 5, lines 63-65). The toothpaste comprises a humectant that may be glycerin or sorbitol in a concentration ranging from 10% to 70% by weight. The water content of the toothpaste disclosed in the reference ranges from 10% to 50%. Thickening agents used in the toothpaste are incorporated in an amount ranging from 0.5% to 5% weight of the composition. Preferred thickening agents are carboxyvinyl polymers, carrageenan, hydroxyethyl cellulose and water-soluble salts of cellulose ethers such as sodium carboxymethyl cellulose and sodium carboxymethyl hydroxyethyl cellulose (col. 15, lines 22-45). The weight percents encompass those recited by the instant claims. The reference anticipates the instant claims insofar as disclosing a composition comprising a polyvalent alcohol, a polymer or carboxymethyl cellulose, and water.

5) Claims 1, 3, 6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Turgeon (US 5,541,165).

Turgeon teaches oral compositions for the relief of dry mouth and for preventing dehydration in sufferers of dry mouth, which forms a saliva substitute in the mouth. The compositions comprise glycerin, water, a pH buffering system, gum, and a pharmacologically acceptable carrier; wherein the percentage by volume of said glycerin is from about 0.16% to about 4.5%, the percentage by volume of water from

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about 25% to about 75%, and the remainder consisting essentially of said gum and pH buffering system in a pharmaceutically acceptable carrier provided in from about 25% to 75% by volume (see claim 1). The reference anticipates the instant claims insofar as disclosing a composition for wetting the mouth comprising a polyvalent alcohol, a polymer, and water and/or artificial saliva. In regards to the composition of the prior art being able to act as a mouth wetting agent for false teeth, since the compositions of the reference are substantially the same, i.e., they include a polyvalent alcohol, a water-soluble polymer, and water and/or saliva substitute, as the wetting agent of the instant claims, accordingly the compositions of the reference should be able to act as a mouth wetting agent for false teeth.

6) Claims 1, 3, 5-6, 8, 10, 12 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Hunter et al. (US 6,159,459).

Hunter et al. teaches oral lubricating compositions. The compositions are used for relieving the soft-tissue disorders associated with xerostomia. They comprise a beta-glucan polymer as an active ingredient (col. 1, lines 6-14). In accordance with the present invention compositions containing beta-glucan polymers for oral application may be in any convenient form, such as a mouthrinse, spray, tablet, lozenge, chewing gum, or toothpaste. The beta-glucan polymer concentrations range from 0.005% to 5.0% by weight. Also included in the compositions are humectants and water. Humectants include glycerol, sorbitol, propylene glycol, polypropylene glycol and/or mannitol, and are incorporated into the compositions at a concentration ranging from

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10-30% by weight. The water makes up 65% to 80% of the compositions (col. 4, first table). The reference anticipates the instant claims insofar as disclosing a composition for lubricating the mouth comprising a polyvalent alcohol, a polymer, and water. In regards to the composition of the prior art being able to act as a mouth wetting agent for false teeth, since the compositions of the reference are substantially the same, i.e., they include a polyvalent alcohol, a water-soluble polymer, and water, as the wetting agent of the instant claims, accordingly the compositions of the reference should be able to act as a mouth wetting agent for false teeth.

Claims 1-16 are rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

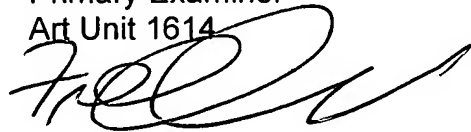
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Lezah Roberts  
Patent Examiner  
Art Unit 1614

A handwritten signature in black ink, appearing to read 'Lezah Roberts', with a stylized, flowing script.

Frederick Krass  
Primary Examiner  
Art Unit 1614

A handwritten signature in black ink, appearing to read 'Frederick Krass', with a stylized, flowing script.